

R E M A R K S

Careful review and examination of the subject application are noted and appreciated.

SUPPORT FOR THE CLAIM AMENDMENTS

Support for the claim amendments may be found in the specification, for example, on page 8 lines 8-15, page 10 lines 25-26 and FIGS. 1 and 2, as originally filed, and page 8 bottom paragraph and FIG. 8 of the October 17, 2005 amendment. Thus, no new matter has been added.

TERMINAL DISCLAIMER

Applicant's representative respectfully requests that the Office accept the terminal disclaimer dated August 21, 2007 because the 5,601,435 patent is assigned to Health Hero Network, Inc.

Assignment reel 008259 frame 0789 shows that US Patent No. 5,601,435 was assigned from Interface Systems, Inc. to Raya Systems, Inc. in November 1995 (see Exhibit A). Raya Systems, Inc. changed its name to Health Hero Network, Inc. in May 1997 (see Exhibit B). The first page of the terminal disclaimer indicated that Health Hero Network, Inc. is the owner of 100% interest in the present application. Both the present invention and the 5,601,435 patent are commonly owned. As such, the terminal disclaimer is proper and should be accepted.

DOUBLE PATENTING

The rejection of claims 48, 50-52, 59, 61, 75-79, and 81-84 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over US Patent No. 5,601,435 has been obviated by the previously filed terminal disclaimer and should be withdrawn.

PRIORITY

The objection to the priority has been obviated by amendment and should be withdrawn. The claim language alleged to lack adequate support has been deleted. As such, priority listing in the application is correct and the objection should be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §112

The rejection of claims 48, 50-52, 55-62, 64, 65, 68-79, 81-84 and 96-122 under 35 U.S.C. §112, first paragraph, has been obviated by amendment and should be withdrawn.

CLAIM REJECTIONS UNDER 35 U.S.C. §103

The rejection of claims 48, 50, 51, 55-62, 64, 68-79, 81-84, and 96-122 under 35 U.S.C. §103(a) as being unpatentable over Brown '263 in view of Miwa '607 has been obviated in part by amendment, is respectfully traversed in part, and should be withdrawn.

The rejection of claims 52 and 65 under 35 U.S.C. §103(a) as being unpatentable over Brown in view of Miwa and Holmes II et al. '687 (hereafter Holmes) has been obviated in part by amendment, is respectfully traversed in part, and should be withdrawn.

Brown concerns a modular microprocessor-based health monitoring system (title). Miwa concerns a system for centralized management of medical data (title). Holmes concerns a glucose test data acquisition and management system (title). In contrast, the present invention provides a blood glucose monitoring system for monitoring a blood glucose level and for providing health-related information. The system generally comprises (a) a display device, (b) an audio speaker, (c) a processor, (d) at least one built-in memory, (e) at least one physiological data monitor, (f) an interface device, (g) an input device (h) and a cable. The display

device may include a display screen which displays the blood glucose level as measured. The processor may be configured to provide audio and visual signals to the audio speaker and display device respectively. The built-in memory may include read-only digital memory (ROM) or writeable digital memory (RAM), or both, having stored therein operation data and operation software routines for (i) controlling the blood glucose monitoring system; (ii) comparing the blood glucose level as measured with stored measurements; (iii) performing one or more further processing functions in response to the comparing; (iv) connecting to a remotely located computer in response to receiving an address of the remotely located computer from a memory card; and (v) receiving the health-related information from the remotely located computer. The physiological data monitor may be configured to (i) provide a measurement signal representative of a physiological parameter of a user and (ii) reside outside a first housing containing said processor. The interface device may be coupled between the processor and the physiological data monitor to at least isolate electrically the physiological data monitor from the processor while coupled therebetween, the electrically isolating interface device being neither entirely disposed within the first housing containing the processor nor any housing containing the physiological data monitor. The input device may be in communication with the processor and configured to (i) receive an input from the user; (ii) enable the user to (1) make selections and (2) control one or more user functions of the blood glucose monitoring system; and (iii) provide a control signal to the processor based upon the input, thereby to cause the health related information to be provided to the user based upon the measurement signal representative of the blood glucose level and the control signal, the physiological parameter including the blood glucose level and the physiological data monitor including a blood glucose

indicator. The cable may couple the interface device to the processor. In contrast, none of the proposed combinations of the references appear to include all of the claim limitations. As such, *prima facie* obviousness has not been established.

Claims 48, 51, 62, 75 and 81 are independently patentable over the cited references. Claim 48 provides (d) at least one built-in memory having stored therein operation data and operation software routines for (iv) connecting to a remotely located computer in response to receiving an address of the remotely located computer from a removable memory card. Claims 51, 62, 75 and 81 provide similar language. The Office Action asserts that (i) Brown teaches obtaining an address of a remotely located computer from a removable memory card in column 13 line 1-16 and (ii) the Data Management Unit 10 of Brown contains data and software similar to the claimed operational data and operational software routines. In contrast, the cited text of Brown does not explicitly mention the Data Management Unit 10. As such, *prima facie* obviousness has not been established that the proposed combination of references includes all of the claimed limitations.

In particular, the cited text of Brown reads:

Such data can be processed, analyzed, printed and/or displayed by computer 62 using commercially available or custom software. On the other hand, various types of analyses may be performed by clearinghouse 54 with the results of the analyses being transmitted to the remotely located healthcare professional 60. For example, clearinghouse 54 can process and analyze data in a manner identical to the processing and analysis provided by the self-care monitoring system of FIG. 1. With respect to such processing and any other analysis and processing provided by clearinghouse 54, results expressed in alphanumeric format can be sent to computer 62 via telephone line 64 and the modem associated with computer 62, with conventional techniques being used for displaying and/or printing the alphanumeric material for subsequent reference.

Nowhere in the above text is the Data Management Unit 10 explicitly mentioned. Nowhere in the above text is an address of a remotely

located computer explicitly mentioned. Nowhere in the above text is a removable memory card containing the alleged address explicitly mentioned. Miwa does not cure these deficiencies. As such, the Office is respectfully requested to either (i) provide a clear explanation of how the cited text of Brown allegedly teaches the claimed address in the claimed removable memory card or (ii) withdraw the rejections.

Claim 48 further provides (d) that operation data and operation software routines are also for (ii) comparing the blood glucose level as measured with stored measurements. Claims 51, 62, 75 and 81 provide similar language. The Office Action asserts that Brown teaches the claimed limitation by mentioning "statistics" in column 11 line 50. In contrast, comparing measured values with stored values does not appear to be inherent to the word "statistics". As such, *prima facie* obviousness has not been established that the proposed combination of references includes all of the claimed limitations.

In particular, the cited line of Brown, in context, reads:

Regardless of whether a compact video game system, another type of commercially available handheld microprocessor-based unit, or a specially designed unit is used, the preferred embodiments of FIG. 1 provide a self-care blood glucose monitoring system in which program cartridge 42: (a) adapts handheld microprocessor unit 12 for displaying instructions for performing the blood glucose test sequence and associated calibration and test procedures; (b) adapts handheld microprocessor unit 12 **for displaying** (graphically or alphanumerically) **statistical data such as blood glucose test results taken during a specific period of time** (e.g., a day, week, etc.); (c) adapts handheld microprocessor unit 12 for supplying control signals and signals representative of food intake or other useful information to data management unit 10; (d) adapts handheld microprocessor unit 12 for simultaneous graphical display of blood glucose levels with information such as food intake; and, (e) adapts handheld microprocessor unit 12 for displaying information or instructions from a healthcare professional that are coupled

to data management unit 10 from a clearinghouse 54. The manner in which the arrangement of FIG. 1 implements the above-mentioned functions and others can be better understood with reference to FIGS. 2 and 3. (Col 11:40-63 Emphasis added.)

The above text of Brown does not explicitly mentioned comparing as alleged in the Office Action. Miwa does not cure this deficiency. As such, the Office is respectfully requested to either (i) explain why one of ordinary skill in the art would allegedly interpret displaying "statistical data such as blood glucose test results taken during a specific period of time" to be similar to the claimed comparing of blood glucose level measurements with stored measurements or (ii) withdraw the rejections.

Claim 48 further provides that (d) the operation data and operation software routines are also for (iii) performing one or more further processing functions **in response to the comparing**. Claims 51, 62, 75 and 81 provide similar language. The Office Action asserts that Brown teaches further processing in response to the comparing in column 11 lines 50-63 (reproduced above). As noted above, the Office Action does not establish that Brown teaches or suggests comparing blood glucose levels with stored measurements. Since the Office Action does not establish the claimed comparing step, the assertion that Brown teaches or suggests further processing functions in response to the missing comparing step cannot be sustained. Miwa does not cure this deficiency. As such, the Office is respectfully requested to either (i) provide a clear explanation of how Brown allegedly teaches the claimed performing further processing functions in response to the alleged comparing or (ii) withdraw the rejections.

Claim 48 further comprises (f) an interface device coupled between the processor and the physiological data monitor to at least isolate electrically the physiological data monitor from the processor while coupled therebetween and (h) a cable coupling

the interface device to the processor. Claims 51, 62, 75 and 81 provide similar language. The Office Action asserts that a cable 18 of Brown is similar to the claimed interface device and that the cable 18 electrically isolates when unplugged. In contrast, the claim has been amended to clarify that the interface device (i) electrically isolates while coupled between the physiological data monitor and the processor and (ii) is coupled to the processor through a cable. As such, *prima facie* obviousness has not been established and the rejections should be withdrawn.

Claims 50, 64 and 84 are independently patentable over the cited references. Claim 50 provides that the interface device includes (a) a signal receiver for receiving the measurement signal representative of the blood glucose level from the at least one physiological data monitor, (b) a converter for converting the measurement signal as received into a form acceptable to the processor and (c) a processor controller for controlling the processor. Claims 64 and 84 provide similar language. The Office Action asserts that (i) the cable 18 of Brown is similar to the claimed interface device and (ii) the claimed signal receiver, converter and processor controller are taught by column 4 lines 49-55 of Brown. In contrast, the cited text of Brown does not explicitly mention the cable 18. As such, *prima facie* obviousness has not been established that the proposed combination of references includes all of the claimed limitations.

In particular, the text in column 4 lines 46-63 of Brown reads:

The lack of provision for the entering of alphanumeric data also can be a disadvantage. For example, currently available blood glucose monitoring systems do not allow the user or the healthcare professional to enter information into the system such as medication dosage and other instructions or data that is relevant to the user's self-care health program.

The above-discussed disadvantages and drawbacks of currently available microprocessor-based blood glucose

monitoring systems also have been impediments to adopting the basic technology of the system for other healthcare situations in which establishing and maintaining an effective regimen for cure or control is dependent upon (or at least facilitated by) periodically monitoring a condition and recording that condition along with time and date tags and other information necessary or helpful in establishing and maintaining a healthcare program.

Nowhere does the above text explicitly mention the cable 18. Nowhere does the above text explicitly mention a signal receiver. Nowhere does the above text explicitly mention a converter. Nowhere does the above text explicitly mention a processor controller. Miwa does not cure these deficiencies. Therefore, the Office is respectfully requested to either (i) clearly explain how the cited text of Brown allegedly teaches the claimed signal receiver, converter and processor controller within the cable 18 of Brown or (ii) withdraw the rejections.

Regarding claims 99, 103, 107, 111 and 115, the text in column 11, lines 40-63 of Brown (reproduced above) cited in the rejection does not appear to explicitly mention an alarm. Therefore, the Office is respectfully requested to either (i) provide a clear explanation of how the cited text allegedly teaches the claimed alarm or (ii) withdraw the rejection.

Regarding claim 118, no arguments are present in the Office Action where the references allegedly teach that the operational data and the operation software routines are configured to recommend a certain action be taken by the user based on the comparing. As such, the rejection of claim 118 should be withdrawn.

Regarding claim 120, no arguments are present in the Office Action where the references allegedly teach that the operational data and the operation software routines are configured to give advice as to diet or exercise habits of the user based on

the comparing. As such, the rejection of claim 120 should be withdrawn.

Regarding claim 122, no arguments are present in the Office Action where the references allegedly teach that the physiological data monitor and the input device are in a second housing separate from the first housing containing the processor.. As such, the rejection of claim 120 should be withdrawn.

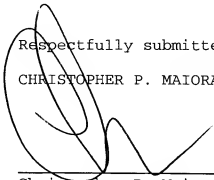
Claims 50, 52, 55-61, 64, 65, 68-74, 76-79, 82-84, 96-115 and 116-122 depend, either directly or indirectly, from claims 48, 51, 62, 75 or 81, which are now believed to be allowable. As such, the dependent claims are fully patentable over the cited references and the rejections should be withdrawn.

COMPLETENESS OF THE OFFICE ACTION

Aside from a notice of allowance, Applicant's representative respectfully requests any further action on the merits be presented as a non-final action. No sustainable arguments were presented for claims 118, 120 and 122 as required by 37 CFR §1.104(b) and MPEP §706.07. As such, the current Office Action is incomplete and prosecution should remain open until all of the claims have been addresses.

Accordingly, the present application is in condition for allowance. Early and favorable action by the Examiner is respectfully solicited.

The Examiner is respectfully invited to call the Applicant's representative at 586-498-0670 should it be deemed beneficial to further advance prosecution of the application.



Respectfully submitted,

CHRISTOPHER P. MAIORANA, P.C.

Christopher P. Maiorana
Registration No. 42,829

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c/o Sandeep Jaggi
Health Hero Network

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